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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,026	10/30/2003	Jeffrey A. Hall	279.401US1	7128

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EXAMINER	
TOY, ALEX B	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,026	HALL ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☒ Claim(s) *11 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In using the term "thermal decay," applicant does not explain how such decay is specifically measured while RF energy is being cyclically reapplied in millisecond intervals. Furthermore, the term "thermal decay" implies only decreases in temperature over time. For the purposes of examination, the term "thermal decay" is interpreted to simply mean a change in temperature over time.

In addition, the specification does not enable one skilled in the art to which it pertains to ascertain how the static thermal properties of the electrode are specifically factored in to determining the duty cycle. Applicant does not disclose an algorithm or other such method for achieving this.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 13-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sherman (U.S. Pat. No. 6,059,778).

Regarding claim 1, Sherman discloses a system for RF ablation comprising:

a catheter 30 having an electrode 16 and a temperature sensor 40 (Fig. 1);

an RF energy source 18 connected to the electrode 16 for delivering RF energy via the electrode (Fig. 1); and

a controller 20 for controlling a duty cycle of the RF energy (col. 3, ln. 49-52), wherein the controller is coupled to the temperature sensor (col. 5, ln. 66-67) and is adapted to change the duty cycle of the RF energy as a function of a thermal decay as determined by a measurement of change of temperature, as measured by the temperature sensor 40, over a time period (Fig. 1). Temperature sensor 40 inherently measures thermal decay as claimed, since duty cycle adjustments by the controller are

in response to a measurement of temperature change over time by the temperature sensor 40 (col. 5, ln. 67 – col. 6, ln. 2).

Regarding claim 2, Sherman discloses the system of claim 1, wherein the controller determines the thermal decay in part as a function of one or more static thermal properties of the electrode. The material of electrodes 32 has a significantly higher thermal conductivity than that of biological tissue, which allows the electrodes to cool off more rapidly in the flowing fluids at the biological site (col. 6, ln. 37-44 and Fig. 1). The power supply may be controlled during ablation to allow for the cooling of the electrodes while at the same time allowing for the temperature of the tissue to build up so that ablation results (col. 6, ln. 44-48).

Regarding claim 3, Sherman discloses the system of claims 1 and 2, wherein one or more static thermal properties of an electrode includes a thermal constant of the electrode. A thermal constant is empirically inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 4, Sherman discloses the system of claims 1 and 2, wherein one or more static thermal properties of an electrode includes a mass of the electrode. A mass is inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 5, Sherman discloses the system of claims 1 and 2, wherein one or more static thermal properties of an electrode includes the surface area of the

electrode. A surface area is inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 6, Sherman discloses the system of claim 1, wherein the duty cycle chosen can range from 1% to 100%. This is inherently possible, and Sherman further discloses operating the electrode at 50% duty cycle (col. 7, ln. 45).

Regarding claim 7, Sherman discloses the system of claim 1, wherein the duty cycle chosen can range from 1% to 20%. This is inherently possible, and Sherman further discloses operating the electrode at 10% duty cycle (col. 3, ln. 53-54).

Regarding claim 8, Sherman discloses the system of claim 1, wherein the duty cycle chosen can range from 80% to 100%. This is inherently possible.

Regarding claim 9, Sherman discloses the system of claims 1 and 2, wherein one or more static thermal properties of the electrode include one or more of mass of the electrode, shape of the electrode, and thermal constant of the electrode. As stated in the preceding rejections of claims 3-5, the temperature sensor 40 inherently considers these properties in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 10, Sherman discloses the system of claim 1, wherein the electrode 16 includes a tip electrode 36 (Fig. 1).

Regarding claims 11 and 13 (a duplicate of claim 11), Sherman discloses the system of claim 1, wherein the electrode 16 includes a ring electrode 32 (Fig. 1).

Regarding claim 14, Sherman discloses the system of claim 1, wherein the electrode includes an array of ring electrodes 32 (Fig. 1).

Regarding claim 15, Sherman discloses the system of claim 1, wherein the RF energy source delivers RF energy having a frequency of 500 kHz, which is in the claimed range of 500-750 kHz (col. 7, ln. 44).

Regarding claim 16, Sherman discloses a system for delivering RF energy to endocardial tissue such as the atrium or ventricle of a heart (col. 6, ln. 8-10), the system comprising:

a catheter 30 having one or more electrodes 32 proximate a distal end of the catheter, the catheter adapted for being positioned such that the one or more electrodes are adjacent the endocardial tissue (Fig. 1). The catheter is designed for and inherently capable of the claimed position; and

a power control system 20 to provide power to the one or more electrodes, the power having a plurality of alternating on portions and off portions, one set of adjacent on and off portions defining a duty cycle (col. 3, ln. 37-38 and col. 7, ln. 41-43, 63-67). This clause of the claim is inherent to the definition of a duty cycle;

wherein the on portions and off portions of the duty cycle are chosen as a function of thermal decay at the electrode and depending on one or more static thermal properties of the one or more electrodes (col. 5, ln. 67 – col. 6, ln. 2). As stated in the preceding rejections of claims 3-5, the temperature sensor 40 inherently considers these properties in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 17, Sherman discloses the system of claim 16, wherein one or more static thermal properties of an electrode includes a thermal constant of the electrode. A thermal constant is empirically inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 18, Sherman discloses the system of claim 16, wherein one or more static thermal properties of an electrode includes a mass of the electrode. A mass is inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 19, Sherman discloses the system of claim 16, wherein one or more static thermal properties of an electrode includes the surface area of the electrode. A surface area is inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 20, Sherman discloses the system of claim 16, wherein one or more static thermal properties of the electrode include one or more of mass of the electrode, shape of the electrode, and thermal constant of the electrode. As stated in the preceding rejections of claims 3-5, the temperature sensor 40 inherently considers these properties in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 21, Sherman discloses the system of claim 16, wherein the electrode 16 includes a tip electrode 36 (Fig. 1).

Regarding claim 22, Sherman discloses the system of claim 16, wherein the electrode 16 includes a ring electrode 32 (Fig. 1).

Regarding claim 23, Sherman discloses a method of RF ablation comprising:

delivering RF energy to a tissue from an electrode (col. 1, ln. 8-10 and col. 3, ln. 29-31);

determining a thermal decay over time proximate the electrode; and

changing a duty cycle of the RF energy in response to the thermal decay.

As stated in the preceding rejection of claim 1, temperature sensor 40 proximate the electrode 32 inherently measures thermal decay as claimed, since duty cycle adjustments by the controller are in response to a measurement of temperature change over time by the temperature sensor 40 (col. 5, ln. 67 – col. 6, ln. 2).

Regarding claim 24, Sherman discloses the method of claim 23, wherein determining a thermal decay includes measuring a temperature proximate the electrode at a first time and at a second later time. As stated in the preceding rejection of claim 1, temperature sensor 40 proximate the electrode 32 inherently measures thermal decay as claimed, since duty cycle adjustments by the controller are in response to a measurement of temperature change over time by the temperature sensor 40 (col. 5, ln. 67 – col. 6, ln. 2). Therefore, the temperature sensor 40 inherently must measure temperature at a first time and at a second later time.

Regarding claim 25, Sherman discloses the method of claim 23, wherein determining a thermal decay includes determining one or more thermal properties of the electrode. As stated in the preceding rejections of claims 3-5, the temperature sensor 40 inherently considers one or more thermal properties of the electrode in measuring the temperature changes used by the controller to determine thermal decay.

Regarding claim 26, Sherman discloses a method of delivering RF energy to endocardial tissue such as the atrium or ventricle of a heart (col. 6, ln. 8-10), the method comprising:

positioning a catheter 30 having one or more electrodes 32 such that at least one of the one or more electrodes is adjacent the endocardial tissue (Fig. 1). The catheter is designed for and inherently capable of the claimed position; and

providing power to the one or more electrodes, the power having a duty cycle with an on portion and an off portion (col. 3, ln. 36-38); and

measuring a temperature proximate the one or more electrodes at two different times, and modifying the duty cycle as a function of a thermal decay as determined by the temperatures measured. As stated in the preceding rejection of claim 1, temperature sensor 40 proximate the electrode 32 inherently measures thermal decay as claimed, since duty cycle adjustments by the controller are in response to a measurement of temperature change over time by the temperature sensor 40 (col. 5, ln. 67 – col. 6, ln. 2). Therefore, the temperature sensor 40 inherently must measure temperature at two different times.

Regarding claim 27, Sherman discloses the method of claim 26, further including modifying the duty cycle depending on one or more static thermal properties of the one or more electrodes. As stated in the preceding rejections of claims 3-5, the temperature sensor 40 inherently considers one or more static thermal properties in measuring the temperature changes used by the controller to determine thermal decay. The controller then modifies the duty cycle based on the thermal decay.

Regarding claim 28, Sherman discloses the method of claim 27, wherein modifying the duty cycle depending on one or more static thermal properties includes modifying the duty cycle depending on a thermal constant of the one or more electrodes As stated in the preceding rejection of claim 3, a thermal constant is empirically inherent to all electrodes. Thus, the temperature sensor 40 inherently considers this property in measuring the temperature changes used by the controller to determine thermal decay. The controller then modifies the duty cycle based on the thermal decay.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-8, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman.

Regarding claims 6-8, Sherman discloses the claimed invention except for the specific duty cycle ranges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the ranges specified in claims 6-8, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 12, Sherman discloses the system of claim 1. Sherman, however, does not expressly disclose that the electrode 16 includes an approximately 5 mm tip with a diameter of approximately 0.094 inches.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the electrode 16 to include an approximately 5 mm tip with a diameter of approximately 0.094 inches because applicant has not disclosed that making the electrode 16 to include an approximately 5 mm tip with a diameter of approximately 0.094 inches provides an advantage, is used in a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate dimensions of Sherman or the claimed approximate dimensions

because on page 8, lines 10-11 of the specification, applicant states that the present system applies to almost any electrode for RF ablation.

Regarding claim 15, Sherman discloses the claimed invention except for the entire range from 500-750 kHz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to claim the range from 500-750 kHz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 4,907,589 to Cosman
U.S. Pat. No. 5,573,533 to Strul
U.S. Pat. No. 5,971,980 to Sherman
U.S. Pat. No. 6,053,912 to Panescu et al.
U.S. Pat. No. 6,117,131 to Taylor

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
8/3/05

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER